



Application No.: 09/580,797

Attorney Docket No.: UNMC63149

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of	)	Group Art Unit: 1634
	)	
Peter Iwen et al.	)	Examiner: J. Goldberg
	)	
Serial No. 09/580,797	)	
	)	
Filed: May 30, 2000	)	
	)	
For: "MATERIALS AND METHODS	)	
FOR MOLECULAR DETECTION	)	
OF CLINICALLY RELEVANT	)	
PATHOGENIC FUNGAL	)	
SPECIES"	)	

DECLARATION OF PETER C. IWEN UNDER 37 C.F.R. §1.132

I, Peter C. Iwen, hereby declare that:

1. I am a citizen of the United States and reside at 6006 Lafayette Ave, Omaha, NE 68132.

2. I received a B.S. degree in Bacteriology from North Dakota State University, and a M.S. degree in Medical Microbiology and Ph.D. degree in Medical Sciences (Infectious Diseases): Internal Medicine, from the University of Nebraska Medical Center. Additional details of my educational background are set forth in my Curriculum vitae, attached hereto.

3. I have over 20 years of experience in the field of microbiology, my particular area of expertise being in infectious disease.

4. I am the author or co-author of over 30 scientific articles on the subjects of medical microbiology, immunology, and medicine. A list of these articles is set forth in my curriculum vitae, attached hereto. My current areas of research include fungal pathogen research.

5. I am a co-inventor of the subject matter disclosed and claimed in U.S. Patent Application Serial No. 09/580,797, entitled "Materials and Methods for Molecular Diagnosis of Clinically Relevant Pathogenic Fungal Species" (hereinafter "the '797 application"), claim 2-5, 20, and 21 are currently under rejection in the U.S. Patent and Trademark Office.

6. I have read and am familiar with the Official Action dated July 25, 2002 and the Advisory Action dated March 11, 2003, in the '797 application. I understand the nature of the rejections made by the Examiner concerning obviousness. I have also read the references cited in connection with the rejections set forth in the Official Action of July 25, 2002 and Advisory Action of March 11, 2003. In particular, I understand that it is the Examiner's position that claims 2-4 and 20 are unpatentable over White et al. (PCR Protocols: A Guide to Methods and Applications, pages 315-322, 1990) and Beck, US Patent 5,827,695, in view of Borsuk et al. (Acta Biochimica Polonica, Vol. 41:73-77, 1994) and Nikkuni et al. (J. Gen. Appl. Microbiol. 44:225-230, 1998) and Pazoutova (GenBank Accession No. AJ001331 (August 1997) and Peterson (GenBank Accession No. U65306 (May 1997) and Aguirre et al. (GenBank Accession No. U93683 (May 1997) and further in view of Sandhu et al. US Patent 5,707,802.

I understand that the Examiner has also rejected claim 5 under 35 U.S.C. §103(a) as allegedly unpatentable over White et

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al. and Beck in view of Borsuk et al. and Nikkuni et al. and Pazoutova and Peterson and Aguirre et al. and further in view of Nelson et al., US Patent 5,827,656.

I understand that the Examiner has further rejected claim 21 under 35 U.S.C. §103(a) as allegedly being unpatentable over White et al. and Beck et al. in view of Borsuk et al. and Nikkuni et al. and Pazoutova and Peterson and Aguirre et al. and further in view of Sandhu et al. and Wang et al., US Patent 5,876,977.

I understand that the Examiner has also rejected claims 21 under 35 U.S.C. §103(a) as allegedly unpatentable over White et al. and Beck in view of Borsuk et al. and Nikkuni et al. and Pazoutova and Peterson and Aguirre et al. and further in view of Sandhu et al. and in further view of Felgner et al., US Patent 6,165,720.

7. As exemplified in the specification, my co-inventors and I have devised an improved method for diagnosing pathogenic fungal infection, and further, for differentiating infectious fungal species. The improved method comprises identification of species specific regions which are isolated using explicit conserved regions. Briefly, in order to provide improved methods for differential fungal pathogen diagnosis, a sample from a patient suspected of having a fungal infection is provided. Two oligonucleotide primers, SEQ ID NO: 1 and SEQ ID NO: 2 are added, the primers bracketing a hypervariable region on the rRNA present on the fungal species in the sample. Then the sequence between the primers is amplified. Next a detectably labeled probe which is directed to a portion of the hypervariable region bracketed by the primers is used to identify the fungal species.

8. None of the references cited by the Examiner teach a primer set which comprises SEQ ID NO: 2. The Examiner has taken the position that the primer sets of White et al., namely ITS1/ITS4 and ITS5/ITS4, are functionally equivalent to the instantly claimed primer set of SEQ ID NO: 1/SEQ ID NO: 2, and thus concludes that the instantly claimed methods are obvious over White et al. It is respectfully submitted that the primer sets of White et al. are not functionally equivalent to the instantly claimed primer set of SEQ ID NO: 1/SEQ ID NO: 2, as the following data will show.

9. Presented herein as Exhibit A are the results of PCR amplification comparing the instantly claimed primer set (SEQ ID NO: 1/SEQ ID NO: 2) and the primer sets of White et al. (ITS1/ITS4 and ITS5/ITS4).

Figure 1 of Exhibit A shows the results of agarose gel electrophoresis and ethidium bromide staining of PCR products from various *Aspergillus* species following amplification of the internal transcribed spacer region utilizing the instantly claimed primer sets, SEQ ID NO: 1 (5'-GGAAGTAAAAGTCGTAACAAGG-3') and SEQ ID NO: 2 (5'-GTATCCCTACCTGATCCGAGG-3').

Figure 2 of Exhibit A shows the results of agarose gel electrophoresis and ethidium bromide staining of PCR products from various *Aspergillus* species following amplification of the internal transcribed spacer region utilizing one the primer sets from White et al, ITS5 (5'-GGAAGTAAAAGTCGTAACAAGG-3') and ITS4 (5'-TCCTCCGCTTATTGATATGC-3'). In Figures 1 and 2, Lanes 1, 2, 3, and 4 contain *A. flavus* as undiluted, 1:10, 1:100, and 1:1000, respectively. Lanes 5, 6, 7, and 8 contain *A. fumigatus* as undiluted, 1:10, 1:100, and 1:1000, respectively. Lanes 9, 10, 11, and 12 contain *A. terreus* as undiluted, 1:10, 1:100, and

1:1000, respectively. Lane N is the negative control and Lane M contains a 100-bp ladder.

A comparison of the data presented reveals that while the fungal primer set consisting of SEQ ID NOS: 1 and 2 amplifies *A. flavus*, *A. fumigatus* and *A. terreus* as the DNA samples are diluted up to 1:100, the ITS5/ITS4 primer set of White et al. is incapable of amplifying *A. fumigatus* and *A. terreus* under these conditions.

These data and the data submitted in the earlier filed Declaration provide clear evidence that neither of the primer sets of White et al., namely ITS1/ITS4 or ITS5/ITS4, is functionally equivalent to the primer set of the instant invention. In contrast to the instantly claimed primer set of SEQ ID NOS: 1 and 2, the primer set of White et al. considered to comprise the closest prior art (i.e., ITS5/ITS4) only weakly amplifies *A. fumigatus* at high primer concentrations and completely loses sensitivity as DNA samples are diluted. Additionally, The ITS5/ITS4 primer set does not amplify *A. terreus* at all when samples are diluted to 1:100 or 1:1000. Accordingly, the Examiner's contention that the primer set ITS5/ITS4 of White et al. is functionally equivalent to those recited in the instant claims is erroneous.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful statements may

jeopardize the validity of the above-referenced application or  
any patent issued thereon.

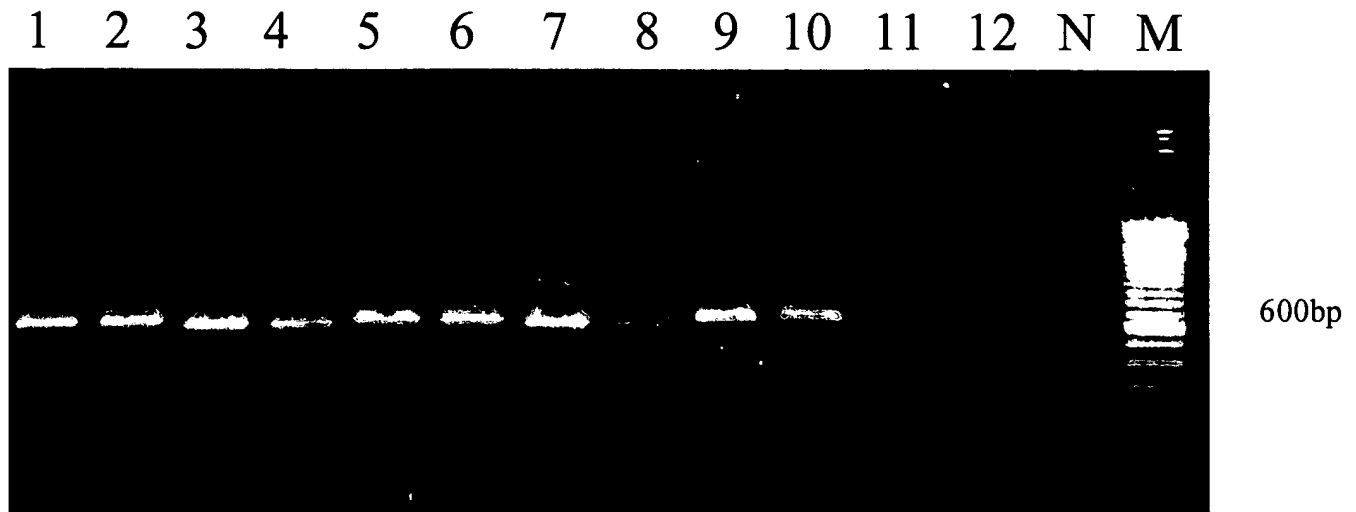
7/24/03

DATE

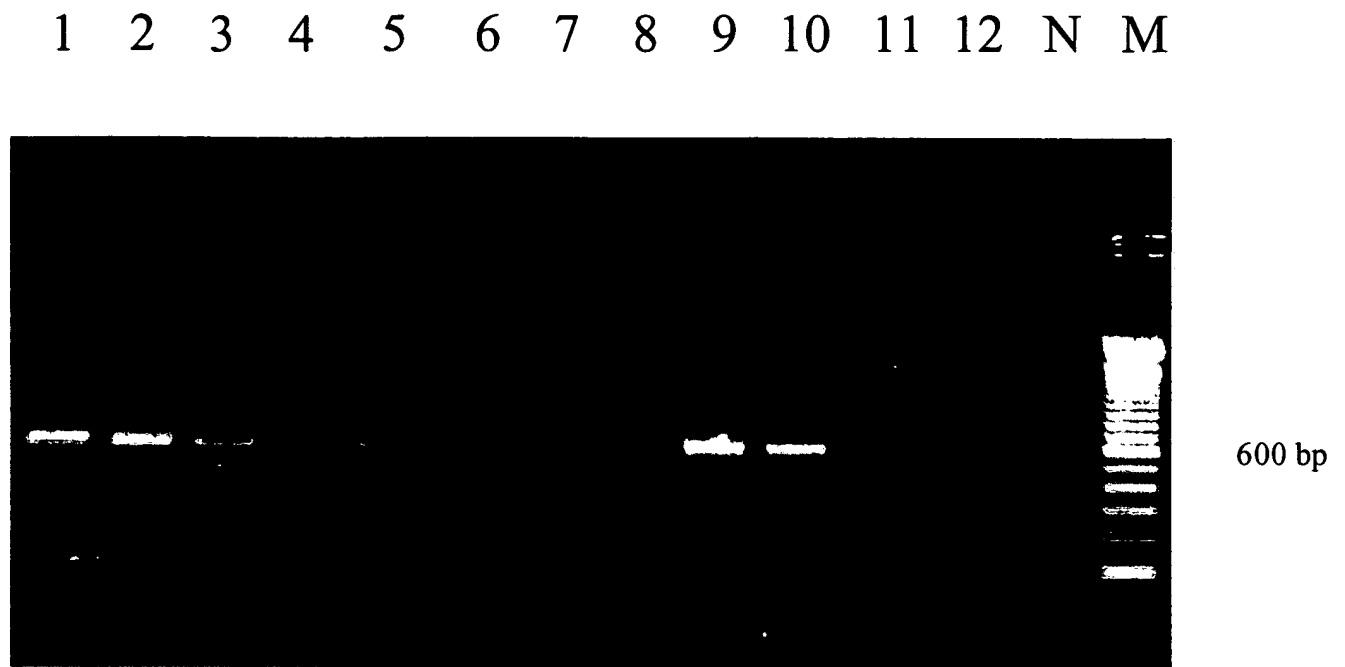
Peter C. Iwen

Peter C. Iwen

## EXHIBIT A

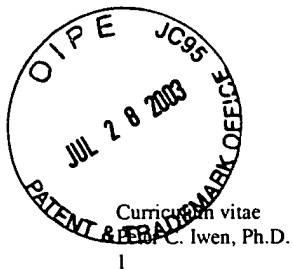


**Figure 1.** Agarose gel electrophoresis of ethidium bromide stained PCR products prepared from DNA samples extracted from various cultured *Aspergillus* species following amplification of the internal transcribed spacer regions. Primer pair used includes SEQ ID NO: 1 (5'-GGAAGTAAAAGTCGTAACAAGG-3') and SEQ ID NO: 2 (5'-GTATCCCTACCTGATCCGAGG-3'). Lanes 1, 2, 3, and 4 all contain *A. flavus* as undiluted, 1:10, 1:100, and 1:1000, respectively. Lanes 5, 6, 7, and 8 all contain *A. fumigatus* as undiluted, 1:10, 1:100, and 1:1000, respectively. Lanes 9, 10, 11, and 12 all contain *A. terreus* as undiluted, 1:10, 1:100, and 1:1000, respectively. Lane N was the negative control and Lane M contained a 100-bp ladder.



**Figure 2.** Agarose gel electrophoresis of ethidium bromide stained PCR products prepared from DNA samples extracted from various cultured *Aspergillus* species following amplification of the internal transcribed spacer regions. Primer pair used includes ITS5 of White et al. (5'-GGAAGTAAAAGTCGTAACAAGG-3') and ITS4 of White et al. (5'-TCCTCCGCTTATTGATATGC-3'). Lanes 1, 2, 3, and 4 all contain *A. flavus* as undiluted, 1:10, 1:100, and 1:1000, respectively. Lanes 5, 6, 7, and 8 all contain *A. fumigatus* as undiluted, 1:10, 1:100, and 1:1000, respectively. Lanes 9, 10, 11, and 12 all contain *A. terreus* as undiluted, 1:10, 1:100, and 1:1000, respectively. Lane N was the negative control and Lane M contained a 100-bp ladder.





## **CURRICULUM VITAE**

September 2002

**NAME IN FULL:** Peter C. Iwen, M.S., Ph.D., M(ASCP), SM(NRM), CLS/M

**SOCIAL SECURITY NO:** 502-60-5133

**ADDRESS:** University of Nebraska Medical Center  
Department of Pathology and Microbiology  
686495 Nebraska Medical Center  
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**PLACE OF BIRTH:** Fargo, North Dakota

### **EDUCATION:**

1997-01	Ph.D., Medical Sciences (Infectious Diseases): Internal Med., University of Nebraska Medical Center, Omaha, NE Thesis, "Characterization of the internal transcribed spacer regions of the rDNA gene complex of human fungal pathogens", September 2001; Advisor, M.E. Rupp, M.D.
1979-82	M.S., Medical Microbiology, University of Nebraska Medical Center; Omaha, NE Thesis, "Treatment of experimental pulmonary cryptococcosis in the immunosuppressed mice with ketoconazole and amphotericin B". December 1982; Advisor, N.G. Miller, Ph.D.
1972-76	B.S., Bacteriology, North Dakota State University; Fargo, ND

### **POST-DEGREE AND CONTINUING EDUCATION TRAINING**

02/1998 to 01/2001	Fulfilled re-certification requirements with the National Certification Agency for Medical Laboratory Personnel as a Clinical Laboratory Scientist in Microbiology. CLS/M Current through January 2004
07/1993 to 06/1998	Fulfilled re-certification requirements with the National Registry of Microbiologists as a Specialist Microbiologist in Public Health and Medical Laboratory Microbiology. SM(NRM) Current through December 2003.

## ACADEMIC APPOINTMENTS:

1996-present	Assistant Professor, University of Nebraska Medical Center, Department of Pathology and Microbiology, Omaha, NE
1986-2000	Instructor, Iowa Western Community College, Nursing Department, Council Bluffs, IA
1993-96	Instructor, University of Nebraska Medical Center, Department of Pathology and Microbiology, Omaha, NE
1988-93	Courtesy Instructor, University of Nebraska Medical Center, Department of Pathology and Microbiology, Omaha, NE

## CERTIFICATIONS AND LICENSES:

1992-present	Clinical Laboratory Scientist in Microbiology. The National Certification Agency for Medical Laboratory Personnel. CLS/M
1988-present	Specialist Microbiologist in Public Health and Medical Laboratory Microbiology. The National Registry of Microbiologists, American Academy of Microbiology. SM(NRM)
1984-present	Microbiologist. American Society of Clinical Pathologists. M(ASCP)

## GRANT/CONTRACT SUPPORT:

10/02 to 09/03	"Development of a microchip for the identification of fungal pathogens" Transgenomic, Inc. Principal Investigator, <b>Peter C. Iwen</b> (\$50,000)
09/02 to 08/03	"Molecular characterization and pathogenesis of <i>Francisella tularensis</i> " Provisional PIs, Mike Meagher/ (\$100,000) Steve Hinrichs Co-Investigator <b>Peter C. Iwen</b>
07/02 to 09/03	"Bioterrorism laboratory service agreement" Principal Investigator Steve Hinrichs (\$900,000) Co-Investigator <b>Peter C. Iwen</b>
01/02 to 10/02	"Practice guideline for treatment of suspected and proven candidiasis with fluconazole in non-neutropenic patients" Pfizer Pharmaceutical Principal Investigator, Phil Smith (\$6,500) Co-Investigator <b>Peter C. Iwen</b>

09/01 to 12/02	<p>“A phase II, randomized, parallel, placebo-controlled, double-blind, multicenter efficacy and safety study of ramoplanin and placebo in neutropenic oncology patients identified as asymptomatic carriers of vancomycin-resistant <i>Enterococcus</i> (VRE)”</p> <p>IntraBiotics Pharmaceuticals, Inc.</p> <p>Principal Investigator, Julie Vose (\$14,500)</p> <p>Co-Investigator <b>Peter C. Iwen</b></p>
09/01 to 08/02	<p>“Evaluation of the WAVE System to identify fungal pathogens”</p> <p>Transgenomic, Inc.</p> <p>Principal Investigator, Steven H. Hinrichs (\$50,000)</p> <p>Co-Investigator <b>Peter C. Iwen</b></p>
09/01 to 03/02	<p>“Dade MicroScan clinical study: dried overnight cation-adjusted antimicrobials for gram-negative organisms, Summer 2001”</p> <p>Dade Bering, MicroScan Division</p> <p>Principal Investigator, <b>Peter C. Iwen</b> (\$14,700)</p>
08/01 to 12/02	<p>“Comparison of hand bioburden in response of various hand hygiene practices”</p> <p>UNMC Clinical Research Center</p> <p>Principal Investigator, Mark Rupp (\$4,000)</p> <p>Co-Investigator <b>Peter C. Iwen</b></p>
04/01 to 04/03	<p>“Chemotherapy alliance for neutropenics and the control of emerging resistance (CANCER) surveillance program”</p> <p>The Jones Group</p> <p>Principal Investigator, <b>Peter C. Iwen</b> (\$18,000)</p>
11/00 to 12/02	<p>“Phase III, randomized, evaluation committee-blinded study to assess the safety and efficacy of topical administration of MBI 226 1.0% gel versus standard medical care in patients undergoing non-cuffed, short-term arterial and/or central venous catheterization”</p> <p>Omnicare Clinical Research</p> <p>Principal Investigator, Austin Thompson (\$300,000)</p> <p>Co-Investigator <b>Peter C. Iwen</b></p>
07/00 to 06/01	<p>“Faculty education support grant”</p> <p>UNMC College of Medicine</p> <p>Principal Investigator, <b>Peter C. Iwen</b> (\$1,600)</p>
06/00 to 06/01	<p>“Application of a new polymerase chain reaction technique for rapid detection and identification of fungal pathogens”</p>

	Merck & Co., Inc. Principal Investigator,	<b>Peter C. Iwen</b>	(\$66,540)
06/00 to 06/01	“Dade MicroScan clinical trial Conventional Antibiotic Qualification 8” Dade Behring, MicroScan Division Principal Investigator,	<b>Peter C. Iwen</b>	(\$32,500)
11/99 to 03/01	“Influenzae surveillance program” R.W. Johnson Pharmaceutical Research Institute Principal Investigator,	<b>Peter C. Iwen</b>	(\$5,000)
09/99 to 12/00	“Enhanced laboratory preparedness” Nebraska Department of Health and Human Services Principal Investigator, Contract Support,	James Wisecarver <b>Peter C. Iwen</b>	(\$140,825)
09/99 to 11/99	“Historic control study of the efficacy of standard therapy in acute aspergillosis to allow comparison with the efficacy of voriconazole” Pfizer Corporation Principal Investigator, Contract Support,	Elizabeth Reed <b>Peter C. Iwen</b>	(\$3,700)
09/99 to 02/00	“Outcomes experience of patients with invasive aspergillosis treated with amphotericin B, lipid formulations of amphotericin B, and/or itraconazole” Merck & Co., Inc Principal Investigator, Co-Investigator,	Edward Dominguez <b>Peter C. Iwen</b>	(\$24,000)
08/99 to 03/00	“North American Zyvox (linazolid) antimicrobial potency study” The Clinical Pharmacokinetics Laboratory Principal Investigator,	<b>Peter C. Iwen</b>	(\$2,250)
07/99 to 11/99	“Moxifloxacin regional and national in vitro susceptibility of common respiratory tract pathogens” Bayer Corporation Principal Investigator,	<b>Peter C. Iwen</b>	(\$5,000)
02/99 to 12/99	“Improving the diagnosis of invasive aspergillosis in immuno-compromised patients” The Liposomal Company Principal Investigator,	<b>Peter C. Iwen</b>	(\$5,000)

10/98 to 06/99	<p>“The impact of <i>Lactobacillus caseii</i> GG on the GI function in short bowel syndrome”</p> <p>ConAgra, Inc.</p> <p>Principal Investigator, Judith D. Sondheimer (\$2,000)</p> <p>Co-Investigator, <b>Peter C. Iwen</b></p>
07/98 to 07/00	<p>A comparison of the Arrowg+ and III antimicrobial surface treated, triple-lumen, central venous catheters vs. standard-triple lumen catheters in a randomized, double-blinded multi center trial”</p> <p>Arrow International, Inc.</p> <p>Principal Investigator, Mark E. Rupp (\$150,000)</p> <p>Contract Support <b>Peter C. Iwen</b></p>
07/98 to 06/99	<p>“Faculty education support grant”</p> <p>UNMC College of Medicine</p> <p>Principal Investigator, <b>Peter C. Iwen</b> (\$1,000)</p>
07/98 to 12/98	<p>“Enterohemorrhagic <i>E.coli</i> prevalence study”</p> <p>State of Nebraska</p> <p>Principal Investigator, Paul D. Fey (\$7,000)</p> <p>Co-Investigator, <b>Peter C. Iwen</b></p>
02/98 to 12/98	<p>“Universal swab equivalency study”</p> <p>GenProbe, Inc.</p> <p>Principal Investigator, <b>Peter C. Iwen</b> (\$24,800)</p> <p>Co-Investigator, Steven H. Hinrichs</p>
07/97 to 06/98	<p>“Enteric decontamination with bacitracin and bismuth subsalicylate in patients colonized with VRE”</p> <p>UNMC Seed Research Grant</p> <p>Principal Investigator, Mark E. Rupp (\$7,500)</p> <p>Co-Investigator, <b>Peter C. Iwen</b></p>
02/97 to 02/98	<p>“Dried overnight gram-positive identification clinical trial”</p> <p>Dade MicroScan International</p> <p>Principal Investigator, <b>Peter C. Iwen</b> (\$5,000)</p>
07/96 to 06/97	<p>“Study of contamination in non-vented closed enteral feeding systems”</p> <p>Clintec Technologies, Inc.</p> <p>Principal Investigator, Mark E. Rupp (\$15,000)</p> <p>Contract Support <b>Peter C. Iwen</b></p>

07/96 to 12/96	"National broad spectrum-lactamase surveillance trial." University of Iowa Hospitals and Clinic. Principal Investigator, Ron Jones Co-Investigator, <b>Peter C. Iwen</b> (\$1,500)		
07/93 to 06/94	"Evaluation of the PACE 2C to detect <i>C. trachomatis</i> and <i>N. gonorrhoeae</i> " Gen-Probe, Inc. Principal Investigator, Gail Woods (\$34,000) Co-Investigator, <b>Peter C. Iwen</b>		

#### PATENTS:

U.S. Application No. 09/580,797 (pending)

#### COLLECTIONS:

##### American Type Culture Collection

8/98	<i>Aspergillus ustus</i>	ATCC 201953
1/99	<i>Gymnascella hyalinospora</i>	ATCC 204275
1/99	<i>Cylindrocarpon lichenicola</i>	ATCC 204306
2/00	<i>Candida glabrata</i>	ATCC MYA-296
7/01	<i>Exiguobacterium aurantiacum</i>	ATCC BAA-333

##### NCBI GenBank Sequences

2/99	<i>Gymnascella hyalinospora</i>	(VAMH 7366)	ITS1-5.8S-ITS2	AF129853
2/99	<i>Gymnascella hyalinospora</i>	(ATCC 204275)	"	AF129854
2/99	<i>Cladophialophora bantiana</i>	(UTHSC94-986)	"	AF131079
3/99	<i>Cylindrocarpon lichenicola</i>	(ATCC204306)	ITS1-5.8S-ITS2	AF133843
5/99	<i>Aspergillus fumigatus</i>	(ATCC 36607)	"	AF138288
5/99	<i>Aspergillus terreus</i>	(ATCC 16792)	"	AF138290
5/99	<i>Aspergillus flavus</i>	(ATCC 16883)	"	AF138287
5/99	<i>Emmerciella nidulans</i>	(ATCC 10074)	"	AF138289
5/99	<i>Aspergillus niger</i>	(ATCC 16888)	"	AF138904
5/99	<i>Aspergillus ustus</i>	(ATCC 201953)	"	AF157507
6/99	<i>Cryptococcus neoformans</i>	(ATCC 32045)	"	AF162916
6/99	<i>Ajellomyces capsulatus</i>	(ATCC 12700)	"	AF156892
6/99	<i>Histoplasma duboisii</i>	(ATCC 24294)	"	AF162917
7/99	<i>Fusarium oxysporum</i>	(ATCC 48112)	"	AF165875
7/99	<i>Fusarium moniliforme</i>	(ATCC 48843)	"	AF165873
7/99	<i>Nectria haematococca</i>	(ATCC 62877)	"	AF165874
7/99	<i>Candida glabrata</i>	(ATCC 15545)	"	AF167993
7/99	<i>Cylindrocarpon destructans</i>	(UAMH 4907)	"	AF172261
7/99	<i>Candida lusitaniae</i>	(ATCC 66035)	"	AF172262

8/99	<i>Pseudallescheria boydii</i>	(patient)	“	AF181558
9/99	<i>Blastoschizomyces capitatus</i>	(patient)	“	AF183911
9/99	<i>Ajellomyces dermatitidis</i>	(patient)	“	AF183912
1/00	<i>Candida albicans</i>	(ATCC 28516)	“	AF217609
1/00	<i>Lactobacillus rhamnosus</i>	(ATCC 53103)	16S-ITS-23S	AF217610
3/00	<i>Malassezia furfur</i>	(ATCC 44344)	ITS1-5.8S-ITS2	AF246896
3/00	<i>Issatchenkia orientalis</i>	(ATCC 6258)	“	AF246989
7/00	<i>Candida tropicalis</i>	(ATCC 750)	“	AF287910
7/00	<i>Candida parapsilosis</i>	(ATCC 22019)	“	AF287909
8/00	<i>Yersinia enterocolitica</i>	(ATCC 27729)	16S-ITS-23S	AF293850
8/00	<i>Bacillus cereus</i>	(clinical isolate)	“	AF293851
9/00	<i>Bacillus anthracis</i>	(Pasteur strain)	“	AY008265
5/01	<i>Sporothrix schencki</i>	(ATCC 14284)	ITS1-5.8S-ITS2	AF364061
9/01	<i>Exiguobacterium auranticum</i>	(ATCC BAA-333)	16S rDNA	AY047481
12/01	<i>Rhizomucor pusillus</i>	(patient)	ITS1-5.8S-ITS2	AF461764
12/01	<i>Pichia jadinii</i>	(patient)	“	AF458091

## OTHER APPOINTMENTS/POSITIONS:

### Nonacademic appointments

2001-present	Biosafety Officer Univer. NE Med. Ctr./ Univer. NE at Omaha/ NE Health Systems
1997-present	Associate Director, Nebraska Public Health Laboratory
1997-present	Special Microbiology Projects Coordinator, Nebraska Health System's Clinical Microbiology Laboratory
1994-97	Clinical Projects Coordinator, University Hospital's Clinical Microbiology Laboratory
1986-93	Supervisor, Pathology and Microbiology University of Nebraska Medical Center
1983-86	Technical Supervisor, Medical Microbiology University of Nebraska Medical Center
1980-83	Laboratory Technologist, Medical Microbiology University of Nebraska Medical Center
1978-80	Laboratory Technician, Medical Microbiology University of Nebraska Medical Center

### Part-time positions

1982-96	Technologist, Clinical Microbiology Laboratory, University Hospital, Omaha
1980-82	Laboratory Technologist, Animal Vaccine Laboratories, Council Bluffs, IA

## CONSULTING POSITIONS:

### Academic

- 1992-present Midwest Student Medical Research Forum,  
Abstract Judge, American Medical Association  
1991-present Student Research Forum,  
Abstract Judge, UNMC Center for Continuing Education

### Government

- 1981-97 Consultant  
University Hospital's Clinical Microbiology Laboratory

### Industry

- 2001-present Transgenomic, Inc., Omaha, NE  
1983-86 Porci-Tec Labs, Inc., Avoca, IA  
1982-86 Modern Veterinary Products, Inc., Ralston, NE

### Editorial duties

- 2000-present Invited reviewer, *Medical Mycology*  
1997-present Invited reviewer, *Diagnostic Microbiology and Infectious Disease*  
1994-present Invited reviewer, *Clinical Infectious Diseases*  
1994-present Invited reviewer, *Infection Control and Hospital Epidemiology*

## MILITARY SERVICE:

None. No obligation

## HONORS AND AWARDS:

- 1998 Travel Award to ASM General Meeting,  
Dade MicroScan, Inc., West Sacramento, CA.  
1997 Scherago-Rubin Award,  
American Society for Microbiology, Washington, D.C.  
1995 Travel Award to ASM General Meeting,  
Dade MicroScan Inc., West Sacramento, CA.  
1994 Travel Award to ASM General Meeting,  
Gen Probe Inc, San Diego, CA.  
1991 Certificate of Merit for Excellence in Teaching,  
American Medical Student Association  
1990 Travel Award to ASM Annual Meeting,  
DIFCO Laboratories, Ann Arbor, Mich.  
1987 Nominee for Outstanding Service to Allied Health Profession,  
First year Physician Assistant Students



## MEMBERSHIPS AND OFFICES IN PROFESSIONAL SOCIETIES:

2002-present	Full member,	American Biological Safety Association
2001-present	Delegate member,	Association of Public Health Laboratories
1985-present	Full member,	American Society for Microbiology
1985-present	Associate member,	American Society for Clinical Pathologists

## COMMITTEE ASSIGNMENTS:

2001 to present	Member,	UNMC Safety Committee University of Nebraska Medical Center, Omaha
2001 to present	Member,	Institutional Biosafety Committee University of Nebraska Medical Center, Omaha
2001 to present	Member,	Bioterrorism Steering Committee Nebraska Health Systems, Omaha
2001 to present	Member,	Policy and Planning Committee Association of Public Health Laboratories, Washington, D.C.
1998 to present	Member,	Infection Control Committee Nebraska Health Systems, Omaha
1986 to 1998	Member,	Infection Control Committee University Hospital, Omaha

## BIBLIOGRAPHY:

### Articles published in scholarly journals

**Iwen, P.C.**, N.G. Miller, and H.W. McFadden, Jr. 1984. Treatment of murine pulmonary cryptococcosis with ketoconazole and amphotericin B. *J. Infect. Dis.*, 149:650.

**Iwen, P.C.** and N.G. Miller. 1986. Enhancement of ketoconazole across the blood-brain barrier of mice by dimethyl-sulfoxide. *Antimicrob. Agents Chemother.*, 30:617-618.

**Iwen, P.C.**, S.J. Booth, and G.L. Woods. 1989. Comparison of media for screening of diarrhetic stools for the recovery of *Clostridium difficile*. *J. Clin. Microbiol.*, 27:2105-2106.

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**Iwen, P.C.** The AIDS epidemic. Past experience, present status, and future prospects. Meeting of the Insurance Women of Omaha. Omaha, NE, February 17, 1992.

**Iwen, P.C.,** J.C. Davis, and B.A. Winfield. An assessment of air quality monitoring following failure of a protective environment to prevent invasive aspergillosis (IA) in neutropenic patients during major construction. 92nd General Meeting of the American Society for Microbiology, New Orleans, LA. May 27, 1992.

**Iwen, P.C.,** S.H. Hinrichs, D.M. Kelly, and E.C. Reed. *Candida krusei* causing invasive candidiasis in compromised patients not treated with fluconazole. 93rd General Meeting of the American Society for Microbiology, Atlanta, GA. May 19, 1993.

**Iwen, P.C.,** R.A. Walker, K.L. Warren, D.M. Kelly, S.H. Hinrichs, and J. Linder. Evaluation of a nucleic acid based test for simultaneously detecting *Chlamydia trachomatis* and *Neisseria gonorrhoeae*

in endocervical specimens. 94th General Meeting of the American Society for Microbiology, Las Vegas, NV. May 27, 1994.

**Iwen, P.C.,** A.E. Rader, D. Kelly, J.C. Davis, M.E. Rupp, E.A. Dominguez, and J. Linder. Selective media for surveillance of vancomycin-resistant *Enterococcus*. ASCP/CAP 1994 Fall National Meeting, Washington, D.C. October 24-26, 1994.

**Iwen, P.C.,** R.A. Walker, K.L. Warren, D.M. Kelly, S.H. Hinrichs, and J. Linder. Comparison of nucleic-acid probe testing with off-site testing for detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* from endocervical specimens. ASCP/CAP 1994 Fall National Meeting, Washington, D.C. October 24-26, 1994.

**Iwen, P.C.,** D.M. Kelly, J. Mockler, and J. Linder. Performance of MicroScan<sup>R</sup> conventional dried panels for identification and detection of ampicillin and vancomycin resistance in *Enterococcus* species. 95th General Meeting of the American Society for Microbiology, Washington, D.C. May 23, 1995.

**Iwen, P.C.,** E.A. Dominguez, D.M. Kelly, M.E. Rupp, and J. Linder. Increase in antimicrobial resistance among blood isolates of enterococci accompanied by a shift in distribution of species. 95th General Meeting of the American Society for Microbiology, Washington, D.C. May 24, 1995.

**Iwen, P.C.** Etiological agents of nosocomial infections in the intensive care unit. Annual Workshop of the Adult Intensive Care Unit Nurses. Omaha, NE. January 15, 1996.

**Iwen, P.C.** and S.H. Hinrichs. Community-acquired invasive aspergillosis in patients requiring admission to the hospital. Annual Meeting of the Missouri Valley Branch of the American Society for Microbiology. Omaha, NE. March 8, 1996.

**Iwen, P.C.,** D.M. Kelly, and S.H. Hinrichs. Ten-year review of *Aspergillus terreus* infection in immunocompromised patients. 96th General Meeting of the American Society for Microbiology, New Orleans, LA, May 20, 1996.

**Iwen, P.C.,** M.E. Rupp, and S.H. Hinrichs. Community-acquired invasive aspergillosis in immunocompromised patients. 97th General Meeting of the American Society for Microbiology, Miami, FL, May 1997.

**Iwen, P.C.,** M.E. Rupp, P. Schreckenberger, and S.H. Hinrichs. Evaluation of the revised MicroScan dried overnight gram-positive identification panel to identify *Enterococcus* species. 98th General Meeting of the American Society for Microbiology, Atlanta, GA, May 19, 1998.

**Iwen, P.C.** Super bugs. Professional Growth Day for the Greater Omaha Area Association for Professionals in Infection Control and Epidemiology. Omaha, NE. June 5, 1998.

**Iwen, P.C.** Overview of microbiology topics for Infection Control personnel. Small Hospital Infection Control Workshop sponsored by the Nebraska Infection Control Network. Omaha, NE, September 26, 1998.

**Iwen, P.C.** Improving the diagnosis of invasive aspergillosis. UNMC Molecular Diagnostic Study Group. Omaha, NE, January 20, 1999.

**Iwen, P.C.,** T.J. Henry, S.R. Tarantolo, and S.H. Hinrichs. ITS sequence identification of novel mould pathogens. Focus on Fungal Infections 9, San Diego, CA., March 1999.

**Iwen, P.C.,** S.R. Tarantolo, L. Sigler, D.A. Sutton, M.G. Rinaldi, R.P. Lackner, D.I. McCarthy, and S.H. Hinrichs. Pulmonary infection caused by *Gymnascella hyalinospora* in a patient with acute myelogenous leukemia. 99th General Meeting of the American Society for Microbiology, Chicago, IL., May, 1999.

**Iwen, P.C.,** S.H. Hinrichs, J.A. Gulizia, and Mark E. Rupp. 2001. Utilization of the internal transcribed spacer gene complex for diagnosis of invasive aspergillosis from formalin-fixed postmortem tissue. 2001 Diagnostic Approaches for Infectious Diseases: Future Promises and Impact on Clinical Management, Infectious Diseases Society of America, Orlando, FL., April 29, 2001.

**Iwen, P.C.,** R. Rennie, D. Ballou, J. Johnston, S. Connell, and B. Zimmer. 2001. Multicenter evaluation of moxifloxacin and gatifloxacin comparing a MicroScan dried overnight panel with an NCCLS reference panel. 101<sup>st</sup> General Meeting of the American Society for Microbiology, Orlando, FL, May 21, 2001.

**Iwen, P.C.** 2002. The role of molecular mycology in clinical medicine. Focus on Fungal Infections 12, Phoenix, AZ, March 21, 2002.

**Iwen, P.C.,** A.G. Freifeld, T.A. Bruening, and S.H. Hinrichs. 2002. Evaluation of the ESP blood culture system with a panfungal PCR assay for the detection of fungal pathogens in human blood. 102<sup>nd</sup> General Meeting of the American Society for Microbiology, Salt Lake City, UT May 21, 2002.

### Submissions

Shearon, E.C., S.H. Hinrichs, D.A. Sutton, M.G. Rinaldi, D.L. McCarthy, D. Sudan, and **P.C. Iwen**. 2002. Correlation of susceptibility testing with clinical response in patients without hematologic malignancies who develop candidemia caused by *Candida lusitanae*. Clin. Infect. Dis. (Manuscript)

Stickle, D.F., D.A. McKenzie, J.A. Landmark, S.J. Pirruccello, G.A. Post, **P.C. Iwen**, and S.H. Hinrichs. 2002. Effect of sterilizing gamma irradiation on bloodspot newborn screening tests and on whole blood cyclosporine and FK-506 measurements. Amer. J. Clin. Pathol. (Manuscript)

Iwen, P.C. 2002. Molecular detection and typing of fungal pathogens. Clinics in Laboratory Medicine. (Book chapter)

**TEACHING ACTIVITIES:** 2001-2002  
Contact hours (ch) per calendar year

**Lectures in team-taught courses**

Introductory mycology	Medical	M-ID 630	1.5 ch
Mycology board review	Medical	M-ID 630	1.5
Parasitology board review	Medical	M-ID 630	1.5
Streptococci	PA/Pharm D	MM 550	2
Chlamydia	PA/Pharm D	MM 550	1
Introductory mycology	PA/Pharm D	MM 550	1
Antifungal agents	PA/Pharm D	MM 550	1
Cutaneous mycoses	PA/Pharm D	MM 550	1
True systemic mycoses	PA/Pharm D	MM 550	1
Opportunistic mycoses	PA/Pharm D	MM 550	1

**Laboratory coordinator and instructor in team-taught courses**

Immunological reagents	Medical	M-ID 630	2 ch
POPS: Tetanus	Medical	M-ID 630	2
POPS: Hypersensitivity	Medical	M-ID 630	2
Microbiological techniques	Medical	M-ID 630	4
Introductory mycology	Medical	M-ID 630	3
Diagnostic virology	Medical	M-ID 630	2
Diagnostic parasitology	Medical	M-ID 630	3
Blood cultures	Medical	M-ID 630	4
Urinary tract infections	Medical	GU core	4
Sexually transmitted diseases	Medical	GU core	2
Diseases of the lower GI	Medical	GI core	2

**Problem-based learning/small group facilitator**

PBL-case 1	Medical	M-ID 630	4 ch
PBL-case 2	Medical	M-ID 630	5
PBL-case 3	Medical	M-ID 630	5
PBL-case 4	Medical	M-ID 630	5
PBL-case 5	Medical	M-ID 630	5
PBL-case 1	Medical	Hematology	5
PBL-case 2	Medical	Hematology	5

**Course coordinator**

Medical Microbiology Laboratory	PA	MM 511	60 ch
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**Graduate students and resident training**

Infectious Diseases residency training and mentor on research projects

Curriculum vitae  
Peter C. Iwen, Ph.D.  
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Pathology residency training and mentor on research projects

**Local, regional, and national educational activities**

Contributor to the "Nebraska Public Health Newsletter"

Participant in local Infectious Disease Weekly Conference

Regional consultant for environmental biological monitoring

Participant in local Infectious Disease Journal Club

Contributor and consultant to numerous articles in "UNMC Today"

Presentations to civic clubs and other organizations

Numerous television, newspaper, and radio interviews on microbiology and infectious diseases topics